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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/508,738

05/18/2005

Eric Simard

24913/04004

9696

24024 7590 12/09/2008  
CALFEE HALTER & GRISWOLD, LLP  
800 SUPERIOR AVENUE  
SUITE 1400  
CLEVELAND, OH 44114

EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

12/09/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com  
dcunin@calfee.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/508,738	<b>Applicant(s)</b> SIMARD ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/15/2008 has been entered.

2. Applicant's amendments/arguments filed on 09/15/2008 is acknowledged and entered into the record. Accordingly, Claims 3-12 and 14-17 are pending and will be examined on the merits.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiserodt et al. (US Patent #6277368) in view of Ferrante et al. (Cancer Chemother. Pharmacol., Vol. 43(Suppl), p. S61-S68, 1999).
6. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.
7. Hiserodt et al. teaches cellular compositions and methods of using them in cancer immunotherapy, particularly humans. "The [compositions] comprise a source of tumor-associated antigen, and a cytokine-secreting cell line (claim 11, 12, 14, 15). The compositions may be tailored for each type of cancer (claim 7 and 8) or for each subject by mixing tumor antigen with a favorable number of cytokine-producing cells, or with a cocktail of such cells producing a plurality of cytokines at a favorable ratio." (See Abstract of Patent #6277368). The whole-cell tumor compositions taught in Hiserodt et al. have been inactivated by methods known in the art, such as with toxins or irradiation (Column 12, 3<sup>rd</sup> paragraph) (claim 3-6). Example 7 of Hiserodt et al. discloses a combination method for treatment using IL4-secreting 4CI 107 cells mixed with autologous tumor cells along with adjuvant chemotherapy agents such as Cisplatin, cisplatin/cyclophosphamide, doxorubicin, or taxol (claims 9-10). Hiserodt et al. also disclose the cells or mixture of cells are in a pharmaceutical excipient (ie. carrier) used to treat patients. Hiserodt et al. does not teach all these components (tumor cells,

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chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Ferrante et al.

8. Ferrante et al. teach the use of chemotherapeutic compounds such as taxane, paclitaxel, doxorubicin, and cisplatin, as anti-cancer agents.

9. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Hiserodt et al. and Ferrante et al. in the same composition for therapeutic purposes such as to treat cancer. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Hiserodt et al. and Ferrante et al. because they both teach compositions useful for the same purpose, to treat cancer. The claimed product can be viewed as a composition comprising a combination of ingredients known in the art to be useful for the same purpose, i.e. In re Kerkhoven analysis (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Hiserodt et al. and Ferrante et al. teach compositions for the use of cancer therapy.

10. Claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Cancer Immunol. Immunother. 1986) in view of Ferrante et al. (Cancer Chemother. Pharmacol., Vol. 43(Suppl), p. S61-S68, 1999).

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11. The claims are drawn to an anti-cancer composition comprising an antigen, an effective amount of at least one immunomodulator chemotherapeutic compound and a pharmaceutically acceptable carrier, wherein said antigen is inactivated tumor cells.

12. Wang et al. teaches a combination treatment of an anticancer agent, CL 259,763 compound, and an inactivated L1210 leukemia composition given to mice challenged with P388 murine leukemia (claim 3). The mice were vaccinated by IP injection of L1210 leukemia cells that had been irradiated with 4,400 R (Materials and Methods, p. 10) (claim 5 and 6). Wang et al. also discloses “the present study shows that CL 259,763 has a number of properties characteristic of a biological response modifier” (p.13, Discussion) and therefore teach the limitations of claims 11 and 12. Wang et al. in addition evaluated the effect of CL 259,763 on IL-2 production in tumor-bearing animals and showed that CL259,763 reversed the impairment of IL-2 production in the tumor-bearing mice. These studies meet the limitations of claim 14 and 15, by showing the presence of IL-2. Wang et al. does not teach all these components (tumor cells, chemotherapeutic agent, carrier) in the **same** composition. This deficiency is made up for by Ferrante et al.

13. Ferrante et al. teach the use of chemotherapeutic compounds such as taxane, paclitaxel, doxorubicin, and cisplatin, as anti-cancer agents.

14. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the components taught by Wang et al. and Ferrante et al. in the same composition for therapeutic purposes such as to treat cancer. One of ordinary skill in the art would have been motivated to do so with a

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reasonable expectation of success by teachings in Wang et al. and Ferrante et al. because they both teach compositions useful for the same purpose, to treat cancer. The claimed product can be viewed as a composition comprising a combination of ingredients known in the art to be useful for the same purpose, i.e. In re Kerkhoven analysis (In re Kerkhoven, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Wang et al. and Ferrante et al. teach compositions for the use of cancer therapy.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the reply filed 09/15/2008.**

### ***Conclusion***

15. Claims 3-12 and 14-17 are rejected.
16. No Claim is allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-

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0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN  
/Larry R. Helms/  
Supervisory Patent Examiner